

REMARKS

Claim 1 has been amended to recite that the appropriate bulky substituents are "selected from the group consisting of 2-(4-diethylamino-2-hydroxy-benzoyl)-benzoic acid hexylester, 4-methyl benzylidene camphor, and methylene bis-benzotriazo tetramethylbutylphenol." Support for this amendment is found in the specification at, for example, page 9, the last four lines to page 10, the first three lines (published International Application WO 2005/048960 is referenced); and original claim 5. See, e.g., *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claim 1 has also been amended to recite "polysilicone-15 (Parsol SLX)" rather than "at least one polysiloxane-based UV filter." Support for this amendment is found in the specification at, for example, page 9, the penultimate paragraph; page 19, row 29, column 1 of the table presented in Example 1; and page 20, row 2, column 1 of the table presented in Example 2.

Claims 2-3 have been canceled without prejudice.

No new matter has been added by any of the amendments.

Obviousness Rejection

Claims 1-3, 6 and 7 have been rejected solely under 35 U.S.C. § 103(a) as being unpatentable over by EP 0 979 645 to Gozenbach *et al.* ("Gozenbach") in view of US patent publication No. 2004/0047817 to Bonda *et al.* ("Bonda") (Paper No. 20110316 at 3).

Gozenbach discloses cosmetic light-screening compositions containing 2-phenylbenzimidazol-sulfonic acid (PBSA) or a salt thereof and a polysiloxane compound (Gozenbach, page 9, lines 55-57). Gozenbach further discloses that this combination of the polysiloxane compound and PBSA or a salt thereof may optionally be used in combination with other known UV-A and/or UV-B filters (*Id.*, page 6, lines 26-28). As suitable UV-B filters and UV-A filters, a large laundry list of compounds is disclosed belonging "to the widest classes of substance" (*Id.*, page 6, line 29 to page 7, line 2).

Bonda discloses "a method of preparing a sunscreen including a solvent system and a filter system, the method including the step of controlling the polarity of the solvent system to control the rate of photodecay of the filter system" (Bonda, Abstract). Bonda also discloses the preferred range of more than 25 cosmetically acceptable photoactive compounds and concentrations for products marketed in the U.S. and in the European Union (Bonda, column 5, line 45 to column 6, line 34).

In making the rejection, the Examiner summarily asserted that Gozenbach discloses "light screening compositions comprising the same polysiloxane-based UV filters as claimed in claims 1, 2, and 3, (page 1-5), the same additional UV filters as claimed in claims 1, 4, 5, and 6, (phenylbenz-imidazole sulfonic acid and 3-benzylidene camphor) (page 6), a carrier (aqueous phase and fatty phase) (abstract), as pertaining to claim 1, and percentages of said polysiloxane-bases UV filter and said additional UV filters as pertaining to the ratio of claim 7 ([19] and claim 8)." (Paper No. 20101008 at 4).

The Examiner, however, acknowledged that Gonzenbach does not "teach percentages for homosalate or that the percentage present for said polysiloxane based UV agent is less than the sum amount of UV filters b) and d) as pertaining to claim 7."

(*Id.*) To fill in the acknowledged gap, the Examiner relied on Bonda because "Bonda teaches that homosalate is typically present up to 10%" (*Id.*)

The Examiner then contended that "[o]ne of ordinary skill' in the art would have been motivated to do this because both references teach to UV agents such as homosalate and Bonda teaches a preferred percentage limit for homosalate in Europe." (*Id.* at 5). The Examiner concluded that "it would have been obvious to utilize up to and including the maximum preferred amount of homosalate of Bonda, in the formulations of Gonzenbach [] in order to use said components in known and preferred amounts." (*Id.*) The Examiner reasoned that "[s]ince Bonda teaches 10% homosalate, Gonzenbach et al. teach 10% phenylbenzimidazole as well as said polysiloxane UV agent preferably present at 20% and more preferably present at 5%, it would have been obvious to produce a formulation in which the combined amounts of homosalate and phenylbenzimidazole are greater than the amount of said polysiloxane UV agent." (*Id.*) The Examiner further concluded that "[f]rom the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention." (*Id.*)

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and modify the document(s) relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness "**analysis should be made explicit**" and the teaching-suggestion-motivation test is "**a helpful insight**" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60

USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify document(s) must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion test “***must be based on objective evidence of record***.” *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). See also *Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) (“The key to supporting any rejection under 35 USC § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.”); *Examination Guidelines Update: Developments in the Obviousness Inquiry After KSR v. Teleflex*, 75 Fed. Reg. 53643, 53645 (September 1, 2010) (“It remains Office policy that appropriate factual findings are required in order to apply the enumerated rationales properly. If a rejection has been made that omits one of the required factual findings, and in response to the rejection a practitioner or inventor points out the omission, Office personnel must either withdraw the rejection, or repeat the rejection including all required factual findings.”).

Here, the rejection is devoid of *any* evidence - or even argument - in support of the proposed combination. All that is there are conclusory remarks and a conclusory statement that “it would have been obvious to utilize up to and including the maximum preferred amount of homosalate of Bonda, in the formulations of Gonzenbach [] in order to use said components in known and preferred amounts.” (Paper No. 20110316 at 5). Bonda discloses preferable concentration ranges of more than 25 photoactive compounds, only one of which is homosalate. Bonda also discloses preferred ranges for photoactive compounds marketed in the U.S. and in the European Union.

Furthermore, it is not clear why the maximum preferred concentration of homosalate for a product marketed in the European Union is to be used.

What the rejection should have done, but did not, was to explain on the record **why** one skilled in this art would (1) select homosalate out of the laundry list of photoactive compounds; (2) select the maximum preferred concentration of homosalate for a product marketed in Europe; and (3) modify the disclosure of Gonzenbach using Bonda to arrive at the claimed invention. As is well settled, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 2007 U.S. App. LEXIS 15349, *12 (Fed. Cir. June 28, 2007) (indicating that "it remains necessary to identify **some reason** that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

As discussed above, to forward prosecution in the present application, independent claim 1 has been amended to recite "(a) polysilicon-15 (Parsol SLX) and (b) at least one additional UV filter which chromophore contains appropriate bulky substituents selected from the group consisting of 2-(4-diethylamino-2-hydroxy-benzoyl)-benzoic acid hexylester, 4-methyl benzylidene camphor, and methylene bis-benzotriazo tetramethylbutylphenol,..." Thus, the claims no longer recite "homosalate."

We also note that “methylene bis-benzotriazo tetramethylbutylphenol” is also known by its tradename, “Tinosorb M” (see page 9, the last line to page 10 the first line of the specification).

The combinations of Parsol SLX and the recited specific additional UV filters having a chromophore with bulky substituents show a surprisingly high SPF and ratio of SPF/UV filter (Σ). For comparison, we take the best-performing formulation disclosed in Gonzenbach, or the formulation that exhibits the most synergy: 5wt% P3 and 1 wt% PBSA.

Composition according to		Gonzenbach	Present Invention		
		Example 4/5	Example 1, formulation 4a	Example 1, formulation 4c	Example 2, formulation 2
Compound recited in (a)	Polysilicone-15 (Parsol SLX)	5	2.5	2.5	4
Compound recited in (b)	Tinosorb M				4 that are 50% active (or 2% active)
	4-methylbenzylidene camphor		4		
	2-(4-diethylamino-2-hydroxy-benzoyl)-benzoic acid hexylester			3	
Other UV filter (compound recited in (d))	Butyl methoxydibenzoylmethane		3		
	Phenylbenzimidazole sulfonic acid	1	2	2	
Total active UV filter content (wt%)		6	11.5	7.5	6
SPF		8.1	31	19	13
Ratio SPF/Σ (total active UV filter		1.35	2.7	2.53	2.1

As shown by the results above, the combination of (a) polysilicone-15 (Parsol SLX) and (b) 2-(4-diethylamino-2-hydroxy-benzoyl)-benzoic acid hexylester, 4-methyl benzylidene camphor, or methylene bis-benzotriazo tetramethylbutylphenol and optionally (d) additional UV filters provide UV-filtering compositions has a surprisingly high SPF and ratio of Ratio SPF/ Σ (UV filter) in comparison with the best performing combination of UV filters disclosed by Gonzenbach.

As is well known, a greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). Thus, it is respectfully submitted that the composition as currently claimed is not obvious in view of the combination of Gonzenbach and Bonda.

The amendments set forth above are believed to place the application in condition for allowance or better form for appeal, and thus are appropriate.

For the foregoing reasons, entry of the amendments and allowance of the claims are respectfully requested. If the Examiner has any questions, please contact the undersigned.

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